

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Liu et al. Serial No.: 11/813,483 Filed: March 29, 2004 For: HIGH CONCENTRATION ANTIBODY AND PROTEIN FORMULATIONS	Group Art Unit: 1644 Examiner: Kim, Yunsoo Confirmation No: 5594 CUSTOMER NO: 09157 Electronically Filed August 31, 2007
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

[X] **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449.

Copies of the items listed on the PTO-1449 form are supplied herewith, except for United States patent(s) and United States patent application publication(s) and other documents that are marked with an asterisk (*) in the attached PTO-1449 form. Copies of United States patents and United States patent application publications will not be supplied unless requested by the Office [37 CFR §1.98(a)(2)(ii)]. See Final Rule **1287 OG** (October 12, 2004). However, copies of any cited document will be provided in its entirety at the request of the Office.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

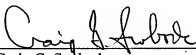
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The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,
GENENTECH, INC.

Date: August 31, 2007

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FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P2026R1	Serial No. 10/813,483		
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Liu et al.			
				Filing Date 29 Mar 2004	Group 1644		
U.S. PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	43	4,093,606	06.06.78	Coval, M.			
	44	4,499,073	12.02.85	Tenold, R.			
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FOREIGN PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
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	62	WO 89/11297	30.11.89	PCT			
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	64	WO 93/05799	01.04.93	PCT			
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)							
	65	Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations" <u>Pharmaceutical Research</u> 8(3):285-291 (1991)					
	66	Bam et al., "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique" <u>Pharm. Res.</u> 12:2-11 (1995)					
	67	Cieland et al., "Development of Stable Protein Formulations for Microencapsulation in Biodegradable Polymers" <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> 22:514-515 (1995)					
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	69	Draber et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose" <u>Journal of Immunological Methods</u> 181(1):37-43 (1995)					
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P2026R1

Serial No.

10/813,483

LIST OF DISCLOSURES CITED BY APPLICANT

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Pikal et al., "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone" Pharm. Res. 8:427-436 (1991)

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Wang et al., "Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers" J. Parenteral Sci. Tech. (Technical Report No. 10) 42(2S):S4-S26 (1988)

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